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# Biotechnology Notes

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**Biotechnology Notes**, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

## INSIDE USDA

### ABRAC REVIEWS NEPA PROCESS

At the June 21-22 meeting of USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC), members were briefed by Milton Robinson, an environmental specialist on detail to the Office of Agricultural Biotechnology (OAB) from the Forest Service, on the purpose of the National Environmental Policy Act (NEPA) and how the Department's draft research guidelines trigger NEPA. Robinson said NEPA is a process which helps public officials make sound decisions concerning the environment.

The major steps in the NEPA process include: 1) publishing in the Federal Register a Notice of Intent to inform the public and others that a federal agency will prepare an environmental impact statement (EIS); 2) identifying potential cooperating agencies and requesting their formal participation and involvement; 3) developing plans for scoping and public involvement; 4) identifying issues and formulating alternatives; 5) preparing the draft EIS; 6) analyzing comments and preparing a final EIS; 7) publishing the EIS; and 8) implementing the decisions and monitoring the results.

Other issues discussed at the meeting were alternatives to the research guidelines, the risk assessment process, and inspection of non-transgenic food animals from transgenic animal experiments.

### NEW USDA BIOTECH COUNCIL MEETS

Food safety was the main topic at the kick-off meeting of USDA's newly formed Biotechnology Council. Chaired by Alvin Young, Director of the OAB, the Council serves as a subcommittee to the Committee on Biotechnology in Agriculture (CBA) and will meet monthly. According to Young, the Council will provide a forum for senior level staffers in 11 agencies and the Office of the Secretary to share information and coordinate biotech programs and activities.

Richard Hall, president of the International Food Biotechnology Council (IFBC), briefed members on a new 400-page report entitled "Biotechnology and Food: Assuring the Safety of Foods Produced by Genetic Modification." (See "A Tomato is a Tomato is . . ." on page 4.) Other issues covered at the meeting included transgenic animals, international research exchanges, and federal-state regulations.

## OECD REPORT MODIFIED

Member countries of the Organization for Economic Cooperation and Development (OECD) are preparing a document on "Good Industrial Large-Scale Practices" (GILSP) which amplifies the concepts that apply to organisms currently outlined in the OECD report entitled "Considerations with rDNA Organisms", as reported at a meeting that took place May 9 and 10 in Paris, France. The modifications were based on descriptions of examples submitted by member countries of genetically modified microorganisms that have been produced using the "good practices" guidelines. GILSP refers to the appropriate practices for the large-scale application of genetically modified organisms. The U.S. delegation included Terry Medley and John Payne from the Animal and Plant Health Inspection Service (APHIS), as well as officials from the Food and Drug Administration, the State Department, the Environmental Protection Agency (EPA), and the Council on Environmental Quality.

## HESS ADDRESSES INTERNATIONAL FORUM

Speaking in Dublin, Ireland, June 6, at the symposium "Harnessing World Benefits of Biotechnology: How Do We Make it Happen?," USDA Assistant Secretary for Science and Education Charles Hess shared his views on the future of biotechnology. He said new advances in biotechnology have led to quicker, more accurate, and less costly means for diagnosing animal and plant diseases. He said biotechnology also affords the opportunity to protect the environment by offering alternatives to chemical pesticides, herbicides, and nitrogen fertilizers.

Internationally, Hess said biotechnology is making significant inroads in improving food production. For example, using in vitro culture for rapid multiplication of virus-free potato seedlings has increased Chinese potato yields by about 150 percent in recent years.

He stressed the need for policymakers to do a better job communicating to the public the regulatory process and other safety oversight mechanisms. Hess said while oversight mechanisms for biotech-derived products are important to ensure safety and public confidence, such mechanisms must not create a burdensome system of oversight which stifles innovation. He also said research and development would suffer if a "fourth criterion" -- socio-economic need -- were added to the review and approval process.

About 80 scientists, government representatives, and European commissioners attended the meeting, which focused on how biotechnology can address global problems. Alvin Young also attended and met with scientists working in animal biotechnology at the University College of Dublin and officials from the Agriculture and Food Development Authority and the Irish Science and Technology Agency.

## FOOD SAFETY CONFERENCE FOCUSES ON CONSUMERS

Biotechnology and food was the focus of a conference held in Ithaca, N.Y., June 11-13, entitled "Agricultural Biotechnology, Food Safety and Nutritional Quality for the Consumer." Workshops covered a range of issues including economic, social and ethical concerns; new diagnostic techniques; communication; food safety; government regulation; and consumer and farmer concerns. One of the highlights was a presentation given by Lester Crawford, administrator of USDA's Food Safety and Inspection Service (FSIS).



Crawford said the FSIS will inspect biotechnology-derived animals under current, science-based regulations. He stressed the need to keep consumers well informed about the regulatory process, and said the agency will share its proposed inspection criteria with ABRAC to ensure all scientific considerations are taken into account.

He said safety assessments for transgenic animals should be similar to those conducted for traditional animals, emphasizing the health of the animal containing the desired trait is an important benchmark of safety.

### . . . OTHER CONFERENCE HIGHLIGHTS

Also speaking at the above conference was Kenneth Taylor, Executive Director for the Minnesota Food Association, who said the current food system is structured to maximize production at the expense of other concerns and that the system overvalues high-technology and undervalues the equitable distribution of wealth and stewardship of the environment.

Carol Tucker Foreman, former USDA Assistant Secretary for Consumer Affairs, said she did not share the widely held belief that lack of consumer confidence in food safety is due mostly to communication problems; rather, she attributes the problem to a difference in the values held by consumers and those endorsed by the biotech community. She called for "Presidential acknowledgement" of the priority of food, health, and safety issues and stressed the need for greater public participation.

### BIOTECH IN BRAZIL

Speaking at a meeting before the Inter-American Study Group on the New Biotechnology In Agriculture and Health, sponsored by the Inter-American Institute for Cooperation on Agriculture (IICA), and held in Brasilia, Brazil, May 29, Deputy Assistant Secretary for Science and Education, Harry Mussman, gave a presentation on the future of biotechnology and its importance to Latin America and the Caribbean.

Terry Medley, director of APHIS's Biotechnology, Biologics and Environmental Protection unit, discussed the role of the Biotechnology Science Coordinating Committee in coordinating and harmonizing regulations nationally. He said the document "Good Developmental Practices for Small Scale Field Research with Genetically Modified Plants and Microorganisms", developed by OECD, served a similar purpose in the international arena.

It was also announced that a workshop will be held on biotechnology biosafety review and regulation in San Jose, Costa Rica this fall. Sponsors include APHIS, IICA and the United Nations Industrial Development Organization.

### NEWS AROUND THE COUNTRY (AND THE WORLD)

#### LATEST STATE SURVEY OUT

A new Industrial Biotechnology Association (IBA) survey of state government legislation on biotechnology is now available. Contents cover bills introduced and the

status of those bills. See page 8 of this newsletter for a map of state legislative initiatives. To receive a copy of the report, call 202-857-0244.

## **A TOMATO IS A TOMATO IS . . .**

A new report on food safety concludes that "existing scientifically sound procedures can be used to assure food safety" and recommends "the regulation of genetically modified food plants and microorganisms be patterned directly on existing laws and practices and that no additional regulatory measures be created for products of biotechnology."

"Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification," outlines "decision trees" to determine the safety of three categories of genetically modified food products: food ingredients from microorganisms, single chemicals, and whole foods and other complex mixtures. Through a detailed question and answer process, one is then led to a decision to accept, reject, or to subject the food product to further study.

The report was prepared by the IFBC, a consortium of 30 companies that use, supply, process, or develop foods and food ingredients. According to its President, Richard Hall, "Foods developed through the new biotechnology must be shown to be as safe as foods that are currently marketed. This report lays out an effective, scientifically sound way to reach that goal."

## **BIOTECH FOR JOURNALISTS ONLY**

A two-week intensive course entitled "Biotech: The Science and the Business" will be held at the University of Maryland's Knight Center for Specialized Journalism, September 30 - to October 12, in College Park, Md. The course will cover basic molecular biology; various lab techniques such as gene splicing, transgenics, and polymerase chain reaction; medical and agricultural applications of biotechnology; and economic and legal issues. Several field trips are planned. Alvin Young has been invited to address the group on government biotech policies and programs.

The Knight Center was established in 1987 to provide reporters and editors with brief but intensive study in subjects such as science, medicine, economics, and the law. The purpose is to improve coverage of these complex fields. The program is open to print and broadcast journalists and admission is by application and selection by a Knight Center committee. The application deadline for the biotech course is August 13. For more information call the Center at 301-454-6423.

## **JAPANESE BIOTECH ASSOCIATION LAUNCHED**

The Japan Bioindustry Association (JBA) has been formed to promote exchanges and cooperation between industry and academia in the field of biotechnology. Industry liaison, a science forum, and research are its three main activities. JBA membership is open to all individuals and organizations. For more information, contact Dr. Yasuki Mori, Director, International Affairs Division, JBA, 10-5, Shimbashi 5-chome, Minato-ku, Tokyo 105, Japan; or call 81-3-433-3545; or FAX inquiries to 81-3-459-1440.



## LARGE-SCALE FIELD TESTS UNDERWAY

The May 1990 issue of BT Catalyst, prepared by the North Carolina Biotechnology Center, reports that the Environmental Protection Agency has issued an experimental use permit to Mycogen Corp. to conduct large-scale field tests of the pesticide MVP in North Carolina and 17 other major vegetable growing states. The purpose of the trials is to verify the performance of MVP when used under a wide variety of use patterns.

MVP was developed using recombinant DNA techniques and is intended to control the diamond-back moth and other caterpillar insects that attack cabbage, broccoli, lettuce, and other crops. MVP cannot multiply or spread because it consists of dead cells.

## IN CASE YOU WEREN'T THERE

- Marshall Phillips, principal scientist on detail to the OAB, gave a paper on risk assessment at the 199th national meeting of the American Chemical Society, held April 22-27 in Boston, Mass. "Minimizing the Risks Associated with Moving Agricultural Biotechnology Research Into the Field" emphasizes the commitment by the USDA to continue to provide leadership and funding for the development and implementation of a program aimed at minimizing the risks related to field testing genetically modified organisms. The program consists of a comprehensive review system, a computerized network for information exchange, a handbook, and a strong commitment to public involvement. The paper was co-authored by Alvin Young and OAB Deputy Director Daniel Jones.
- Transgenic animal models, production, and technology were the topics discussed at the 22nd Annual Laboratory Animal Medicine Conference, April 26-27, at the University of Cincinnati, Ohio. Scientists evaluated the guidelines and regulations for using transgenic animals, procedures for modifying the mammalian genome, animal models for producing therapeutic protein, gene therapy, cryopreservation of mouse embryos, fertilization, and embryo transfer.
- The Office of Technology Assessment, the scientific arm of the U.S. Congress, held a workshop in Washington, D.C. May 9-11 on animal technology. The purpose was to focus on the impact of biotechnology on agriculture and the potential issues that may ensue. Participants discussed productivity, food safety, environmental quality, socioeconomics, and legal and ethical issues of animal technology. Daniel Jones moderated the session on transgenics.
- Public Voice for Food and Health Policy, a public interest group, sponsored a workshop, "Biotechnology and the Food Supply," in Brussels, Belgium, May 31-June 1. The workshop brought together U.S. and European government officials, consumer leaders and industry representatives to discuss food policy questions raised by biotechnology. Topics included the political climate for regulation of biotechnology in Europe, food safety regulation, public information needs, and setting the research agenda. Charles Hess emphasized the need to apply biotechnology to address competitiveness, protecting the environment, and food safety. He said USDA views biotech research as critical in meeting our need for more efficient and environmentally sound agricultural production systems.

## NEW PUBLICATIONS

- Analytical Chemistry of Bacillus thuringiensis. Edited by L. A. Hickie and W. L. Fitch. American Chemical Society Symposium Series No. 432. July 1990. \$34.95. To order call 800-ACS-5558 toll free.
- "Minutes of USDA's Agricultural Biotechnology Research Advisory Committee Meeting," held January 10-12, 1990. To receive a copy at no charge, call the OAB at 202-447-9165.
- "Minutes of the Guidelines Working Group of USDA's Agricultural Biotechnology Research Advisory Committee Meeting," held February 26-28, 1990. To receive a copy at no charge, call the OAB at 202-447-9165.
- Agricultural Bioethics: Implications of Agricultural Biotechnology. Edited by Steven Gendel, A. David Kline, D. Michael Warren, and Faye Yates. April 1990. Published by the Iowa State University Press. \$34.95. To order call 515-292-0155.
- "Mapping Domestic Animal Genomes: Needs and Opportunities" Summary of conference held at the University of Illinois April 8-10. To receive a copy call Lawrence Schook at 217-244-5616.
- "Biotechnology and Food: Assuring the Safety of Foods Produced by Genetic Modification." Prepared by the IFBC. June 1990. To receive the executive summary, call 202-659-0789. The complete report will be published as a supplement to the November/December issue of Regulatory Toxicology and Pharmacology.
- "Agricultural Biotechnology: Environmental Choices and Challenges." Reprint of presentation prepared by Maryln Cordle and Alvin Young, OAB, and delivered at the ECOINFORMA conference May 16 in Bayreuth, West Germany. The article appears in Toxicological and Environmental Chemistry, Vol. 28, pp. 25-35. Copies may also be obtained by calling the OAB at 202-447-9165.
- BIotechnology Education is a new journal intended for teachers who wish to introduce aspects of biotechnology into their existing courses. The journal includes simple, tested class experiments to illustrate practical applications. For a free sample copy, write to Pergamon Press, Headington Hill Hall, Oxford OX3 0BW, England.
- Agricultural Biotechnology: Prospects for the Third World. Published by the Overseas Development Institute. London, England. 1990. To order write to Overseas Development Institute, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, England.
- Briefbook: Biotechnology, Microbes and the Environment. June 1990. Prepared by the Center for Science Information. San Francisco, Calif. \$17.50. Call 415-553-8772.

## UPCOMING MEETINGS

**July 8-13:** Fifth European Congress on Biotechnology. Copenhagen, Denmark. Write to ECB-5, Secretariat, Spadille Congress Service, Sommervej 3, DK-3100 Hornbaek, Denmark.



July 10-12: The Second National Conference on Federal and State Regulation of Biotechnology. Sacramento, Calif. Sponsored by USDA's APHIS. Call Shirley Ingebritsen at 301-436-5874 for details.

July 28-29: "Biotechnology: GMP's, GLP's, and Other Regulatory Issues." Orlando, Fla. Call 703-941-8790.

July 30-31: Annual Meeting of the American Society of Agronomy, North Central Branch. St. Paul, Minn. Includes a special session entitled "Getting Biotech Into the Field" and a tour of a biotech field plot. Call 612-625-8215.

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Aug. 12-18: Symposium on Genetics of Industrial Microorganisms. Strasbourg, France. Write to Societe Francaise de Microbiologie, 28, rue du Docteur Roux-75724, Paris, Cedex 15, France.

Aug. 15-16: Ag Biotech International: Business Opportunities for the 90's. Spokane, Wash. For details write to: Ag Bureau, P.O. Box 2147, Spokane, Wash. 99210.

Aug. 21-24: Conference on Biotechnology and Environmental Science: Molecular Approaches. Bangkok, Thailand. Call Ray Rodriguez at the University of California, Davis, at 916-752-3263.

Aug. 23-30: Fifth International Congress of Ecology: Development of Ecological Perspectives for the 21st Century. Yokohama, Kanagawa, Japan. Sponsored by the Science Council of Japan and the Ecological Society of Japan. Call 615-574-0390.

Aug. 26-31: 200th American Chemical Society National Meeting. Washington, D.C. Call 202-872-4396.

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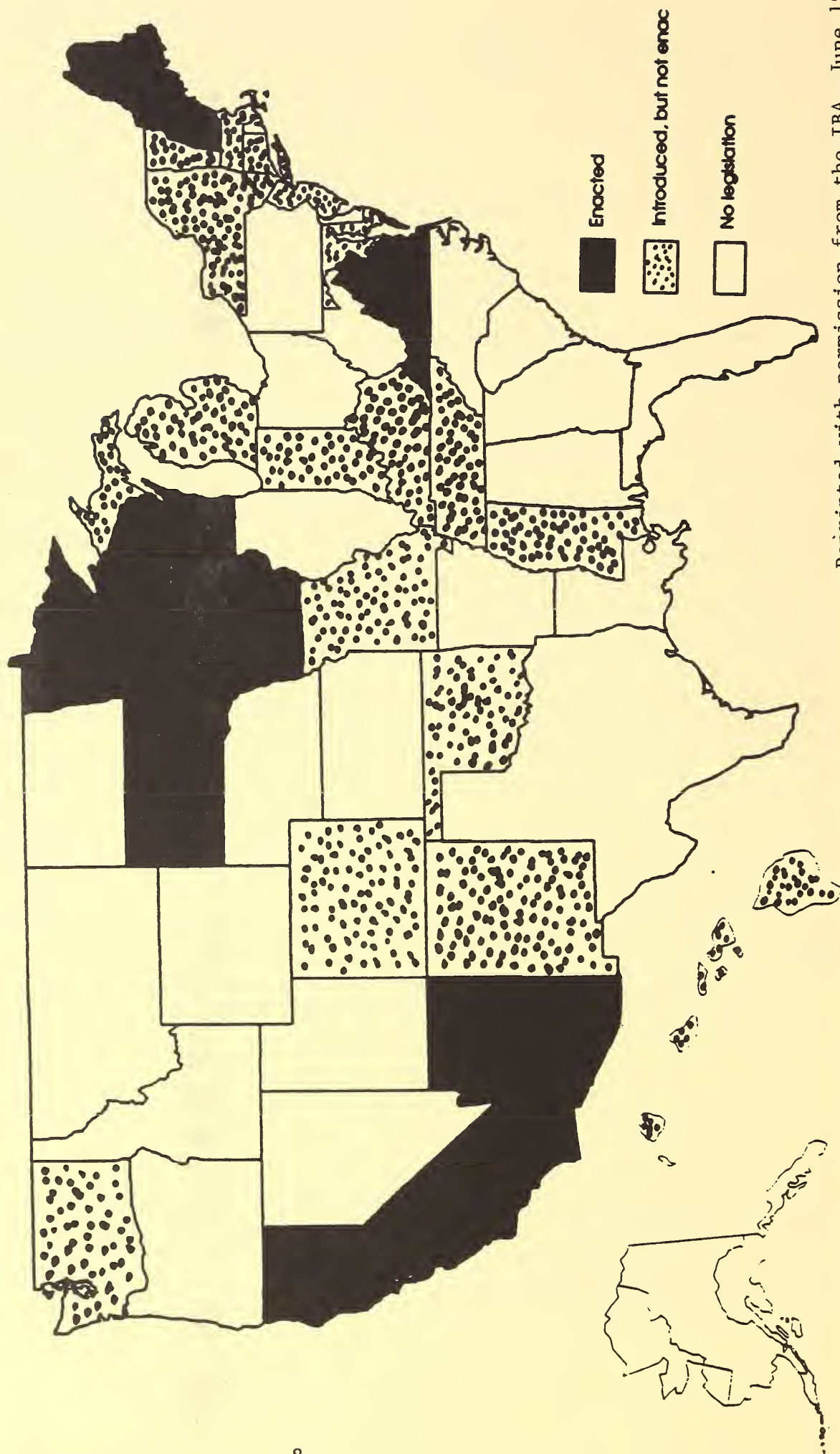
Sept. 12-13: Workshop on Biopesticide Registration Issues. Washington, D.C. Sponsored by the IBA and the Environmental Protection Agency. Call 202-857-0244 for details.

Sept. 18-20: Biotechnica '90. Hannover, West Germany. Call 609-987-1202; FAX 609-987-0092.

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The Industrial Biotechnology Association  
**1990 State Legislative Initiatives in  
 Biotechnology**



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